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IN THE

Supreme Court of the United States

October Term, 1963

No. 833

SIDNEY STEINSCHREIBER, doing business as SID-CAPS LABORATORIES, JOHN P. CALISE, WEST-CHESTER BLOOD SERVICE, INC.,

Petitioners,

against

UNITED STATES OF AMERICA,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

[redacted]

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PETITIONERS' BRIEF

To The Supreme Court of the United States:

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit entered in the above entitled case on January 17, 1964, hereto annexed and marked "Appendix A".

CITATIONS TO OPINIONS BELOW

Subsequent to indictment (*vide* Appendix "B" annexed hereto), petitioners made motions to dismiss same predicated upon a failure of the Government to set forth an offense chargeable under the statute under which said indictment was drawn; the motion was denied by District Judge Sylvester J. Ryan, in *U. S.* v. *Steinschreiber*, reported at 218 F. Supp. 426 (S. D. N. Y., 1962), and his opinion was reproduced in Appellants' Appendix, pp. 5A-8A. Petitioners were permitted to register continuing objections to the admission of Government's expert testimony at the trial, and at the close of Government's case petitioners moved to dismiss indictment. The motion was denied and judgment rendered against petitioners by District Judge Harold R. Tyler, Jr., in *U. S.* v. *Steinschreiber et al.*, 219 F. Supp. 373 (S. D. N. Y., 1963), reproduced opinion in full, in Appellants' Appendix, pp. 9A-33A.

JURISDICTION

The criminal offense charged was prosecuted in the United States District Court for the Southern District of New York, based upon a statute regulating the production of biological products under the commerce clause of the Constitution of the United States (Appellants' Appendix, pp. 91A, 93A, 95A, 97A, 99A). Upon conviction, appeal was taken to the United States Court of Appeals for the Second Circuit, where judgment was affirmed *per curiam*, based upon the opinion of the Trial Court (*vide* Appendix "A"). This petition for a writ of certiorari followed.

QUESTIONS PRESENTED FOR REVIEW

1. Does the statute include, within its express terms, the activities for which the petitioners have been indicted and convicted?

2. Was it error for the District Judge to admit concededly expert testimony by Government witnesses for the purpose of defining the terms and scope of a penal statute?

STATUTE INVOLVED

The prosecution was based upon the Act of July 1, 1944, c. 373, Title III, section 351, 58 Stat. 702, as amended by the 1953 Reorganization Plan No. 1, sections 5 and 8, eff. April 11, 1953, 18 F. R. 2053, 67 Stat. 631, which has been codified as Title 42 U. S. Code, sec. 262. (pp. 91A, 93A, 95A, 97A, 99A, Appellants' Appendix.)

STATEMENT

Petitioners were indicted by the Grand Jury in and for the Southern District of New York (62 Cr. 310) filed April 2, 1962. Thereafter, a superseding Indictment was found against petitioners herein (62 Cr. 797) on August 16, 1962 and subsequently, petitioners were indicted on still another superseding Indictment (62 Cr. 919) on October 10, 1962. The petitioner Steinschreiber was charged in the First Count thereof, with conspiracy to violate the Biological Products Control Act (Sec. 262, T. 42, U. S. Code, and Sec. 371, T. 18, U. S. Code), and in the remaining Counts of engaging in the preparation and sale, in interstate and foreign commerce, of normal human blood plasma, and in

falsely labeling the same, without a license issued by the Secretary of the Department of Health, Education and Welfare. Petitioners Calise and Westchester Blood Service, Inc., were only charged with conspiracy under the First Count to furnish petitioner Steinschreiber with liquid human blood and contributing to the cost of manufacturing this human blood into normal human blood plasma.

Petitioner Steinschreiber moved to dismiss the Indictment (62 Cr. 310) on the ground that the offense as charged was not included within the prohibition of the statute (42 U. S. C. 262), and, that said statute, if it did include the offenses as charged, was unconstitutional because of vagueness. Petitioner Calise joined in the motion, which was denied by Chief Judge Sylvester J. Ryan on May 25, 1962 and thereafter motions to dismiss Indictment (62 Cr. 919) were likewise denied on same grounds by Judge Ryan on October 26, 1962.

The final superseding Indictment (62 Cr. 919) was moved for prosecution. The cause proceeded to trial on April 8, 1963, before Judge Harold R. Tyler, Jr., sitting without a jury in accordance with petitioners' due consent thereto.

In the course of the trial, the Court admitted expert testimony on behalf of the Government concerning the intent, construction and definition of the statutory provisions. To this, petitioners herein made due and timely objection, at many points throughout the trial. The trial was concluded on the 26th day of April, 1963. Petitioners renewed their respective motions to dismiss the Indictment at the close of the entire case; decision was reserved. Thereafter, on the 1st day of July, 1963, in accordance with its written opinion (28th day of June, 1963) and supple-

mental opinion (July 29, 1963), the Court found petitioner Steinschreiber guilty on all Counts except the Ninth, which was dismissed on motion, and petitioners Calise and Westchester Blood Service, Inc., were found guilty on the First Count. The Court pronounced sentence on petitioner Steinschreiber on the 2nd day of August, 1963, and sentenced him to a term in prison for ninety (90) days with a two-year probation commencing at the end of the ninety-day term; petitioner Calise was sentenced to a term of sixty (60) days imprisonment, and upon completion of the term of imprisonment, to two (2) years probation and Westchester Blood Service, Inc., was fined $500.00. Motions of the petitioners herein to set aside the verdict of the Court were denied.

Thereafter, the petitioners were re-sentenced on the 20th day of August, 1963, wherein petitioner Steinschreiber was sentenced to three (3) months imprisonment on Counts 1 to 8 and 10 to 15, concurrently, and execution of sentence was suspended on Count one and probation of two (2) years to commence after expiration of sentence on Counts 2 to 8 and 10 to 15. Petitioner Calise received a re-sentence to six (6) months confinement, of which two (2) months were to be spent in confinement, and the balance of four (4) months to be suspended, with two (2) years of probation. The renewal of the motions of the petitioners to set aside the verdict of the Court was denied.

The appeal was argued before the Court of Appeals for the Second Circuit on January 9, 1964; the Court rendered its *per curiam* opinion and affirmed the judgment of the District Judge on January 17, 1964. (Appendix "A" herein). No motion for rehearing has been made to the Court of Appeals for the Second Circuit. Petitioners were

permitted to remain on bail of $2000.00 pending a determination of the instant Petition.

Petitioners do not dispute the facts as outlined in the opinion of Tyler, D. J., and so far as the facts are material to the issues of law raised in this petition, are willing to follow the same procedure utilized in the Court of Appeals, namely they are willing to accept the statement of facts given in the opinion of the District Judge, as reproduced in Appellants' Appendix, pp. 7A-33A.

REASONS FOR GRANTING THE WRIT OF CERTIORARI

1. Despite the relative antiquity of the statutory provisions, this is a case of first impression in which the existing decision of the District Court does not adequately resolve the questions of statutory interpretation.

The original enactment concerning biological products was passed in 1902, at a time when the use of whole human blood transfusions was highly dangerous to human life, and normal human blood plasma was unknown to medical science. After the successful use of normal human blood plasma in the period 1935-1944, the 1902 statute was reenacted in what is materially the same form, in 1944. Thus the regulation of biological products today is substantially identical, in its statutory basis, with the regulatory plan that was originally enacted in 1902. (Appellants' Appendix, pp. 90A, 92A, 94A, 96A, 98A.)

Despite the existence of this body of statutory law, there has never before been a prosecution, under this statute, of

a person accused of preparing or selling normal human blood plasma, without a license from the Public Health Service. Now, nearly thirty years after the discovery of normal human blood plasma and its medical uses, and twenty years after the re-enactment of the 1902 statute there arises the first case of a prosecution for such a breach of the statutory provisions.

The difficulty of interpreting this statute is vastly increased by the fact that neither the Government nor Petitioner's counsel could find a single case defining the operative words in the statute; for this reason resort was had to decisions defining those words as contained in other Federal statutes.

In writing his opinion the learned District Judge inadvertently overlooked the historical fact, that the medical uses of blood were nearly totally unknown in 1902, and imputed to Congress an intention to regulate the preparation of normal human blood plasma. He also erred in concentrating his attention upon the provision of the Public Health Service Regulations, 42 C.F.R. 73.1 (i) (5). (ii) which mentions blood plasma but not *human* blood plasma (Appellants' Appendix, pp. 102A, 103A); in so limiting the scope of his inquiry he leaves unexplained the question of why there is now in the Code of Federal Regulations, not only the biological products regulation from which he quoted, but also regulations for whole blood (human) and packed red blood cells (human)—*but no regulation concerning normal blood plasma (human)*! These oversights, although brought to the attention of the Court of Appeals, were affirmed by them without opinion. Unless certiorari is granted by this Court, they will continue to define Federal law in this area.

2. Petitioners have been deprived of their constitutional rights by an indictment and conviction predicated upon a statute which does not by its express terms, or its plain meaning, proscribe the activity in which they participated.

This Court recently considered a similar situation to that presented in this case, namely conviction upon an indictment which failed to charge an offense included within the scope of the statute, *Wright* v. *Georgia*, 373 U. S. 284, 83 S.Ct. 1240, 10 L.Ed. 2d, 349 (1963). In that case the conviction was for an offense allegedly against the breach of the peace statute, but the indictment did not charge an offense within the limits of that admittedly broad statute; this Court reversed the conviction.

The instant case entails a similar variance between statute and indictment; it presents a case in which petitioners were deprived of their constitutional rights, not by an unconstitutionally vague statute, but rather by a prosecution founded upon an unconstitutionally broad interpretation of the statute. Such a case makes the strongest appeal that the Supreme Court exercise its supervisory powers, for in refusing to grant a motion to dismiss such an indictment, the Courts of the United States are made party to an unconstitutionally broad interpretation of a penal statute. The unconstitutionality involved here is not the action of Congress, but rather the proceeding of the United States Attorney as approved by the Federal judiciary.

A. The statutory language, as interpreted in the indictment, is not adequate notice that the offense charged was prohibited by Congress.

Petitioners and the Government differ upon the scope of the terms, "Therapeutic serum • • • or analogous product • • •"; it is Petitioners' contention that the terms are so limited as to exclude, affirmatively, normal human blood plasma from their coverage. The Government, on the other hand, points to the alleged chemical similarities between "serum" and "blood plasma"; the continued "acquiescence" of the pharmaceutical industry in Public Health Service regulation of human blood plasma preparation; and upon the Petitioners' "knowledge" that the Public Health Service had customarily undertaken such "regulation" and "acceptance" of human blood plasma as a "therapeutic serum or analogous product."

As Petitioners argued below, there is strong historical evidence against the Government's assertions (*vide* hereto Appendix "C" Excerpts from Steinschreiber Briefs). Failure to comply with trade custom alone, cannot subject Petitioners to criminal sanctions for local and trade custom has been denied any potency in Federal criminal law, *Burnett* v. *U. S.*, 222 F. 2d 426 (6th Cir., 1955), *Smith* v. *U. S.*, 188 F. 2d 969 (9th Cir., 1951), *U. S.* v. *Weinberg*, 226 F. 2d 161 (3rd Cir., 1955). It is further submitted that Petitioners' knowledge of the statute is presumed as a matter of law; their knowledge is not material to the question of what the statute means.

B. The Courts below have unconstitutionally broadened an outdated statute in an effort to include, within its terms, the activities of petitioners; in doing so, they have exceeded their judicial powers and have trespassed upon the legislative powers constitutionally vested in Congress.

This is a hard case that is destined to make bad law if certiorari is not granted. Clearly some supervision of human blood plasma production is in the public interest and within the powers of Congress. Judges being human share the all too human tendency to picture themselves as victims of a contaminated blood transfusion. While Petitioners state, in passing, that no deleterious results have been noted because of their activities, they strongly urge upon this Court that the principle of the separation of legislative from judicial powers requires that regulation of normal human blood plasma preparation must proceed *not* from the decision of a Judge, but rather from a statute of Congress. Unpopular though his decision may be and may seem to him, personally, it is the solemn duty of a Federal court to refrain from taking action where Congress has failed to act with regard thereto.

The Government persuaded the Courts below that by reenacting the Biological Products Control Act in 1944, and by making appropriations for the Public Health Service from 1939 to the present date, Congress acquiesced in that agency's regulation of normal human blood plasma. In this contention the Government is unsupported by any historical evidence; in fact its position is negated by a close inspection of the Congressional committee report and the appropriation acts (*vide* Appendix "C" herein). Ir-

quendo, even if such could be considered the intention of Congress would this have been adequate notice under the void for vagueness doctrine laid down by this Court in *U. S.* v. *Cohen Grocery Co.*, 255 U. S. 81, 41 S. Ct. 298, 65 L. Ed. 516 (1921), *Lanzetta* v. *New Jersey*, 306 U. S. 516, 59 S. Ct. 618, 83 L. Ed. 888 (1939)?

Further proof of the antiquity of this statute is the crude technique of delegating authority to the Public Health Service, again derived from the 1902 statute. The delegation is one of authority to issue licenses pursuant to the statute, to establish standards of cleanliness in production, and to inspect establishments producing biological products; there is *no* delegation of authority to issue regulations defining the statutory terms *nor* to add new products as developed by medical science. It is the Government's erroneous contention, now adopted by the Courts below, that this is adequate delegation of authority upon which the Public Health Service may prescribe standards for new products *not* included *nor* defined within the scope of the statute.

C. The Government should not have been permitted to introduce its expert witnesses to interpret the terms and scope of the statute over due and timely objection.

Three expert witnesses submitted their personal opinions on Government's case, concerning the definitions of the terms "therapeutic", "serum", "plasma", and "analogous", *and, in their testimony*, further assured the Trial Judge that "normal human blood plasma was a product analogous to therapeutic serum." The Government argues that since the trial herein was before a Judge, without a

jury, no reversible error occurred. However Petitioner fails to understand why a Judge would not be as much influenced by the opinion of these testimonial experts as a jury would have been. What occurred in this case was the unlawful substitution of experts to delineate the intent, meaning, definition and construction of the Statute for the District Judge and prejudice his interpretation of the statute concerned. This cannot be countenanced in the annals of Federal criminal law administration.

3. There is no statute, nor any administrative regulation, proscribing the petitioners' alleged criminal activity.

As noted in 1(B), above, the statutory delegation of powers to the Public Health Service is in such terms as to render impotent any interpretive regulations by the Service. However even if the interpretive power is conceded to the Public Health Service, it is impossible to find any regulation of the Service which would serve as a warning to Petitioners that their anticipated activities were contrary to regulations.

A. The regulations do not contain a section providing for the regulation of normal human blood plasma production.

The Government bottoms its case upon that portion of the Regulations which related to therapeutic serums, despite the fact that there are separate and distinct regulations concerning whole blood (human) and packed red blood cells (human), 42 C.F.R. 73.300 *et seq.*, 42 C.F.R. 73.320 *et seq.* The Government fails to explain why a simi-

lar regulation has *not* been issued for normal blood plasma (human). If normal human blood plasma is encompassed within the terms "therapeutic serum", why did the Public Health Service find it necessary to issue separate and distinct regulations concerning the source of normal human blood plasma—i.e. whole blood (human)—, and for one of the products which, like normal human blood plasma, is obtained from whole blood (human)?

It should be noted that in his opinion the learned Trial Judge referred to 42 C.F.R. 73.1 (i) (5) (ii) which refers to "* * * whole blood or plasma", but which does not specify that it is *human*, as contradistinguished from animal blood, which is intended! The Government strenuously argued below, by its counsel and its experts, that a human being is an animal; if this contention is accepted, the Trial Judge's conclusion concerning the regulatory provision may be correct. Petitioners do not now urge this Court to review Darwin's theory of evolution, but deferentially submit that Federal criminal law will be in a sorry state, indeed, when lawyers and judges identify humans with animals for the purposes of administering the penal statutes.

B. Since there is no promulgated regulation concerning normal human blood plasma, petitioners could not have had notice, as a matter of law, that their activities were proscribed.

Only one document has been found to state the Public Health Service's attitude toward normal human blood plasma. It is an office memorandum which by the policy of the Service, printed upon the face of the memorandum, *is not to be made available generally.* (Govt's Appendix,

p. 254a, bottom of opposite page). It has *never* been printed in the Code of Federal Regulations! Such a document cannot be considered legally binding upon Petitioners, in fact it has no force whatsoever because it fails to meet the constitutional requirement of due notice of the scope of a penal statute! The document is mentioned here to indicate to the Court the haphazard techniques which the Public Health Service has used in the attempt to supervise the sanitary conditions under which blood plasma is prepared. (Govt's Exh. 62, p. 254a, Govt's Appendix). The Public Health Service has been totally negligent of the public interest in this regard. It has failed to seek or request Congress to pass a new statute or to amend the old statute. It has failed to issue a regulation concerning normal human blood plasma in the Code of Federal Regulations! It has now "cornered" individuals, who, in its opinion, have violated the "gentleman's agreement" between the Public Health Service and the "pharmaceutical industry." It has sought, and obtained, the assistance of the Attorney General's office in indicting and convicting these men; and in the process of obtaining the convictions, has prevailed upon the District Judge and the Court of Appeals, an appeal so effective, that it caused them to overlook the constitutional rights of the accused. Should the Public Health Service be permitted to make the Courts of the United States a party to their belated attempt to take circuitous action in this field without seeking the enactment of legislation by Congress?

CONCLUSION

The Court should, in the exercise of its supervisory powers, grant the petitioners a writ of certiorari for the purpose of reviewing the judgment of conviction and affirmance in the Courts below.

Respectfully submitted,

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